803. Misbranding of castor oil. U. S. v. 29⅔ Dozen Bottles of Castor Oil. Default decree of condemnation and destruction. (F. D. C. No. 7575. Sample No. 89773–E.)

On May 29, 1942, the United States attorney for the Southern District of New York filed a libel against 29⅔ dozen bottles of castor oil at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about April 21, 1942, by Ritchie & Janvier, Inc., from Bloomfield, N. J.; and charging that it was misbranded in that it would be dangerous to health when used in the dosage recommended in the labeling, namely, "Dosage: Infants Up to 1 year, 1 tablespoonful." The article was labeled in part: "Kellogg's Perfected Tasteless Castor Oil."

On July 22, 1942, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

804. Misbranding of Dr. Hand's Worm Elixir. U. S. v. 23½ Dozen Bottles of Dr. Hand's Worm Elixir. Decree of condemnation and destruction. (F. D. C. No. 7137. Sample No. 31378–E.)

On April 1, 1942, the United States attorney for the Eastern District of Michigan filed a libel against 23½ dozen bottles of Dr. Hand's Worm Elixir at Detroit, Mich., alleging that the article had been shipped in interstate commerce by Smith, Kline & French Laboratories from Philadelphia, Pa., on or about February 17, 1942.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs, including santonin and a laxative drug, in a vehicle of syrup, a small proportion of alcohol, and flavoring material. Santonin was present in solution to the extent of 0.164 gram per 100 cubic centimeters and in the sediment to the extent of 0.065 gram per 100 cubic centimeters.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency or duration prescribed in the labeling, since the amount of santonin provided by the article when used in accordance with such directions was sufficient to produce serious poisoning. The dosage recommended was as follows: "DOSE—2 to 4 years, 1 teaspoonful; 4 to 6 years, 1½ to 2 teaspoonfuls; 6 to 10 years, 2 to 3 teaspoonfuls; adults, 4 teaspoonfuls. Give first dose at bedtime, second dose the first thing the following morning and third dose two hours later. Give a light diet while using the medicine. Do not repeat treatment for seven days. If the bowels have not moved freely within two hours after the third dose, give an enema or a quick acting cathartic, such as Epsom salt or citrate of magnesia until free movement has occurred. Do not give an oily cathartic."

On August 7, 1942, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[2]

805. Adulteration and misbranding of Cherry Balsam and misbranding of Arabian Oil liniment, Mentho-Thymoline, Mettozone Tablets, Climax C. & P. R., and Bu-U Diuretic. U. S. v. Standard Drug Co., Inc. Plea of nolo contendere. Fine, $5.00. Fine suspended during good behavior. (F. D. C. No. 6446. Sample Nos. 37487–E to 37489–E, incl., 37796–E to 37799–E, incl.)

These products were misbranded because of false and misleading curative and therapeutic claims in the labeling and were further misbranded in the following respects: The labels of the Arabian Oil and the Mettozone Tablets, the former a rubefacient containing ammonia and turpentine and the latter containing zinc phosphide and cantharides, failed to bear necessary and adequate warning statements; the Cherry Balsam contained a smaller amount of chloroform than declared, the Mentho-Thymoline failed to bear a statement of the quantity of the contents and the cartons of the Cherry Balsam, Arabian Oil, Climax C. & P. R. and the Bu-U Diuretic were much larger than was necessary to hold the bottles.

On August 4, 1942, the United States attorney for the Western District of South Carolina filed an information against the Standard Drug Co., Inc., Spartanburg, S. C., alleging shipment on or about February 28 and March 13, 1941, from the State of South Carolina into the States of North Carolina and Georgia of quantities of the above-named drugs, all of which were misbranded; the Cherry Balsam was also adulterated.

[2] See also Nos. 837, 845.

Analysis of a sample of the Cherry Balsam showed that it consisted essentially of extracts of plant drugs, chloroform 0.76 minim per fluid ounce, sugar, and water. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 2 minims of chloroform per fluid ounce, whereas it contained not more than 0.76 minim of chloroform per fluid ounce. It was alleged to be misbranded (1) in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of chronic coughs; (2) in that its container was so made, formed, and filled as to be misleading; and (3) in that the statements, "Chloroform 2 minims to Fl. Oz.," and "Each Fluid Ounce Contains 2 minims Chloroform," were false and misleading.

Analysis of a sample of the Arabian Oil showed that it consisted essentially of soap, ammonia, turpentine, and water. It was alleged to be misbranded (1) in that it was a rubefacient, containing ammonia and turpentine and might cause irritation of the skin, particularly if applied with rubbing, and it should not be allowed to get into the eyes or on the mucous membranes and its labeling did not bear warnings to that effect; (2) in that its labeling bore false and misleading representations regarding its efficacy in the cure, treatment or prevention of pain incident to rheumatism, lame back, stiff joints, croup, swellings, wounds, etc.; and (3) in that its container was so made, formed, and filled as to be misleading.

Analysis of a sample of the Mentho-Thymoline showed that it consisted essentially of small proportions of camphor, menthol, and thymol, incorporated in a petrolatum base. It was alleged to be misbranded (1) in that its labeling bore false and misleading representations regarding its efficacy in the cure or treatment of inflammations, colds, croup, sore throat, burns, wounds, piles, headache, and earache; (2) in that the name "Mentho-Thymoline" was misleading, since it suggested that the article consisted solely of menthol and thymol, whereas it did not so consist, but did contain other active ingredients; and (3) in that its label failed to bear an accurate statement of the quantity of the contents.

Analysis of a sample of the Mettozone Tablets showed that they consisted essentially of small proportions of extracts of plant drugs, including nux vomica, and a phosphide of some metal such as zinc. It was alleged to be misbranded: (1) In that it contained zinc phosphide, the frequent or continued use of which might lead to chronic phosphorus poisoning, and it contained cantharides, the use of which might cause nausea, vomiting, and abdominal pain and might seriously injure the kindeys, and its labeling did not warn of such dangers, and its use by persons afflicted by disease of the kidneys might be especially dangerous; (2) in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of sexual debility, weakened sexual powers, or impotency.

Analysis of a sample of the Climax C. & P. R. showed that it consisted essentially of extracts of plant drugs including capsicum, chloroform, alcohol, and water. It was alleged to be misbranded in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of pain in the bowels, cramp, colic, and diarrhea; and in that its container was so made, formed, and filled as to be misleading.

Analysis of a sample of the Bu-U Diuretic showed that it consisted essentially of extracts of plant drugs, small proportions of potassium acetate, alcohol, and water, preserved with sodium benzoate and colored with caramel. It was alleged to be misbranded in that representations in the labeling that it was a diuretic and would strengthen the kidneys and would assist in eliminating poisons and wastes from the system were false and misleading since it was not a diuretic, and would not be efficacious for the purposes claimed; and in that its container was so made, formed, and filled as to be misleading.

On September 14, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of $5.00 and ordered that payment be suspended during good behavior by the defendant.

806. Adulteration and misbranding of W. K. Sterline's Compound. U. S. v. Webster K. Sterline (W. K. Sterline). Plea of guilty. Fine, $700; payment of $600 suspended. (F. D. C. No. 6417. Sample No. 5019-E.)

On March 7, 1942, the United States attorney for the Southern District of Ohio filed an information against Webster K. Sterline, trading as W. K. Sterline at Sidney, Ohio, alleging shipment on or about December 30, 1940, from the State